Supreme Court, U.S.
FILED
DEC 21 2001
CLERK

(5)

No. 01-441

IN THE

Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITIONERS' SUPPLEMENTAL BRIEF IN RESPONSE TO RESPONDENT'S SUPPLEMENTAL BRIEF

KATHRYN F. GREEN
THE KLEBERG LAW FIRM
800 North Shoreline Blvd.
Suite 900, North Tower
Corpus Christi, Texas 78401
(361) 693-8500

BRIAN WOLFMAN
(Counsel of Record)
SCOTT L. NELSON
PUBLIC CITIZEN
LITIGATION GROUP
1600 20th Street, NW
Washington, D.C. 20009
(202) 588-1000

Attorneys for Petitioners

December 2001

4pp

PETITIONERS' SUPPLEMENTAL BRIEF IN RESPONSE TO RESPONDENT'S SUPPLEMENTAL BRIEF

Respondent has filed a supplemental brief directing the Court's attention to the Eighth Circuit's recent en banc decision in *Brooks v. Howmedica, Inc.*, ___ F.3d ___, 2001 WL 1568430 (Dec. 11, 2001). *Brooks* held that a state-law failure-to-warn claim concerning a device that had undergone FDA pre-market approval ("PMA") was preempted by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act. Respondent explains, at some length, why it believes that *Brooks* is correctly decided, a point that is irrelevant if, as is the case here, there remains a significant split in appellate authority on the question presented that will persist without this Court's intervention.

As to the merits in *Brooks*, only two points are noteworthy. First, *Brooks* presented only the narrow question whether a failure-to-warn claim is preempted by the MDA in light of the approval process for the device at issue in that case. It did not address all failure-to-warn claims and it did not consider other types of damages claims, such as those alleging design defect, manufacturing defect, and violation of a state consumer protection statute, which are presented here and in many of the other decisions that have divided the federal and state courts. Second, the holding in *Brooks*, limited as it is, is flatly at odds with 21 C.F.R. 814.39(d)(2). That provision "relieves any tension between Brooks's failure-to-warn claim and the FDA's ongoing oversight of [the product's] labeling," Resp. Supp. Br., App. 27a (Bye, J., joined by Heaney, J., dissenting), because it explicitly allows manufacturers to add new label warnings and contraindications to enhance consumer safety without prior FDA approval. *See also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497 n.16 (1996) (relying on 21 C.F.R. 814.39(d)(2)).

Respondent also uses *Brooks* to attempt to distinguish two of the principal no-preemption decisions at the heart of the split in appellate authority. First, respondent asserts that *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), can be ignored because the device there was marketed under a different approval process from the one at issue here. But that point is irrelevant in light of *Oja*'s rationale. *Oja* found that the FDA had mandated at least one warning that constituted a specific federal "requirement" within the meaning of 21 U.S.C. 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was premised on "a general [state-law] duty ... 'to inform users and purchasers of potentially dangerous items of the risks involved in their use.'" *Id.* at 789 (quoting *Lohr*, 470 U.S. at 501). Indeed, despite respondent's claim to the contrary, the Eighth Circuit characterized *Oja*'s holding in the same manner as do petitioners. *See* Resp. Supp. Br., App. 17a, 18a. That holding is correct under *Lohr*. More important for present purposes, if that holding were applied here petitioners' general state-law claims would not be preempted. Put differently, *Oja* is irreconcilable with the decision below.

Second, respondent also attempts to distinguish *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which, in direct contrast to the decision below, held that PMA approval does not trigger preemption of state-law damages claims. Despite that holding, respondent suggests that, under *Goodlin*'s rationale, preemption might occur where the agency approval contains an "'ascertainable requirement in an express FDA' order or regulation." Resp. Supp. Br. at 2 (quoting *Brooks*, in turn quoting *Goodlin*). However, PMA approvals are not issued as device-specific agency orders or regulations, but rather under highly general FDA form letters applicable to all PMA devices. *See Goodlin*, 167 F.3d at 1377. In any event, even if one could properly infer a narrower reach to the *Goodlin* holding such an inference would do nothing to eliminate the split in authority between *Goodlin* and the

decision of the Fifth Circuit below. As noted in the petition (at 3-4), *Goodlin* and the decision below came to opposite results *regarding the same medical device marketed under the same FDA approval letter*. It is difficult to conceive of a cleaner split in authority warranting this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Brian Wolfman
(Counsel of Record)
Scott L. Nelson
Public Citizen Litigation Group
1600 20th Street, N.W.
Washington, D.C. 20009
(202) 588-1000

Kathryn F. Green
The Kleberg Law Firm
800 North Shoreline Boulevard
Suite 900, North Tower
Corpus Christi, Texas 78401
(361) 693-8500

Attorneys for Petitioners

December 2001